



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stephen Robert Bloom, Mohammad Ali Ghatei, Caroline Jane Small, Catherine Louise Dakin

Serial No.: 10/541,526

Art Unit: 1646

Filed: July 7, 2005

Examiner: Not Yet Assigned

For: *MODIFICATION OF FEEDING BEHAVIOUR*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including (3) pages of Form PTO-1449 and copies of document (28) cited therein.

Pursuant to the waiver in the notice entitled "Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications Filed After June 30, 2003" published on August 5, 2003 in 1273 OG 55, a copy of cited U.S Patents and Published Applications are not enclosed. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-3129.

### U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,026,685	06-25-1991	Boublik, et al.	514/13
5,574,010	11-12-1996	McFadden	514/12
5,604,203	02-18-1997	Balasubramaniam	514/12
5,696,093	12-09-1997	Tseng, et al.	514/14
6,046,167	04-04-2000	Balasubramaniam	514/13
6,191,102	02-20-2001	DiMarchi, et al.	514/2
6,608,098	08-19-2003	Nagase, et al.	514/411
6,620,910	09-16-2003	Calas, et al.	530/324

### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 619 332	10-12-1994	Kuraray Co., Ltd.	EP
0 795 562	09-17-1997	Kyowa Hakko Kogyo Co., Ltd.	EP
WO 93/19175	09-30-1993	Thorens Bernard	PCT
WO 99/43707	09-02-1999	Novo Nordisk A/S	PCT
WO 00/42026	07-20-2000	Novonordisk AS and Agouron Pharma	PCT
WO 00/59887	10-12-2000	Neurogen Corporation	PCT
WO 00/78333	12-28-2000	Eli Lilly & Co.	PCT
WO 01/04156	01-18-2001	Zealand Pharmaceuticals A/S	PCT
WO 01/14368	03-01-2001	Viropharma Incorporated	PCT
WO 01/35988	05-25-2001	Novo Nordisk A/S	PCT
WO 01/66135	09-13-2001	Novo Nordisk A/S	PCT
WO 01/89554	11-29-2001	Bionebraska, Inc.	PCT
WO 02/03978	01-17-02	Metabasis Therapeutics, Inc & Sankyo Company, Ltd	PCT
WO 02/66479	08-29-2002	Banyu Pharmaceutical Co., Ltd	PCT
WO 02/67918	09-06-2002	Banyu Pharmaceutical Co., Ltd	PCT
WO 03/022304	03-20-2003	IC Innovations	PCT

### Publications

ADRIAN, et al., "Effect of peptide YY on gastric, pancreatic, and biliary function in humans," *Gastroenterology*, 89:494-499 (1985).

CUMMINGS, et al., "A preprandial rise in plasma ghrelin levels suggests a role in meal initiation in humans", *Diabetes*, 50:1714- 1719 (2001).

DAKIN, et al., "Repeated ICV administration of oxyntomodulin causes a greater reduction in body weight gain than in pair-fed rats", *Am J Physiol Endocrinol Metab.*, 283(6):E1173-7 (2002).

DAKIN, et al, "Oxyntomodulin inhibits food intake in the rat", *Endocrinology*, 142:4244-4250 (2001).

ENG, et al., "Isolation and characterization of exendin-4, an exendin-3 analogue, from *Heloderma suspectum* venom. Further evidence for an exendin receptor on dispersed acini from guinea pig pancreas", *J Biol Chem*, 267:7402-7405 (1992).

ENGLISH, "Food fails to suppress ghrelin levels in obese humans", *J Clin Endocrinol Metab*, 87:2984-87 (2002).

GHATEI, et al., "Molecular forms of human enteroglucagon in tissue and plasma: plasma responses to nutrient stimuli in health and in disorders of the upper gastrointestinal tract", *J Clin Endocrinol Metab*, 57:488-495 (1983).

KREYMANN, "Glucagon-like peptide-1 7-36: a physiological incretin in man", *Lancet*, 2:1300-1304 (1987).

TATEMOTO, "Isolation and characterization of peptide YY (PYY), a candidate gut hormone that inhibits pancreatic exocrine secretion", *Proc. Natl. Acad. Sci.*, 79:2514-8 (1982).

UESAKA, et al., "Glucagon-like peptide isolated from the eel intestine: effects on atrial beating", *J Exp Biol.*, 204(Pt 17):3019-26 (2001).

WREN, et al., "Ghrelin enhances appetite and increases food intake in humans", *J Clin Endocrinol Metab*, 86:5992-5 (2001).

WYNNE, et al., "Subcutaneous oxyntomodulin reduces body weight in overweight and obese subjects: a double-blind, randomized, controlled trial", *Diabetes*, 54(8):2390-5 (2005).

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Rivka D. Monheit

Reg. No. 48,731

Dated: November 4, 2005

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(404) 879-2160 (Fax)



Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

**Complete if Known**

<b>Application Number</b>	<b>10/541,526</b>
<b>Filing Date</b>	<b>July 7, 2005</b>
<b>First Named Inventor</b>	<b>Stephen Robert Bloom</b>
<b>Group Art Unit</b>	<b>1646</b>
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	<b>AI 9250US</b>

Sheet	2	of	3
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## FOREIGN PATENT DOCUMENTS

[illegible]

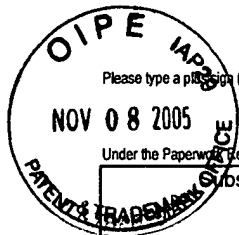
## OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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PTO/SB/08A (10-96)  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				<b>Application Number</b>	
				10/541,526	
				<b>Filing Date</b>	
				July 7, 2005	
				<b>First Named Inventor</b>	
Stephen Robert Bloom					
<b>Group Art Unit</b>					
1646					
<b>Examiner Name</b>					
<b>Attorney Docket Number</b>					
AI 9250US					

Sheet	3	of	3
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Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ADRIAN, et al., "Effect of peptide YY on gastric, pancreatic, and biliary function in humans," <i>Gastroenterology</i> , 89:494-499 (1985).	
		CUMMINGS, et al., "A preprandial rise in plasma ghrelin levels suggests a role in meal initiation in humans", <i>Diabetes</i> , 50:1714- 1719 (2001).	
		DAKIN, et al., "Repeated ICV administration of oxyntomodulin causes a greater reduction in body weight gain than in pair-fed rats", <i>Am J Physiol Endocrinol Metab.</i> , 283(6):E1173-7 (2002).	
		DAKIN, et al, "Oxyntomodulin inhibits food intake in the rat", <i>Endocrinology</i> , 142:4244-4250 (2001).	
		ENG, et al., "Isolation and characterization of exendin-4, an exendin-3 analogue, from <i>Heloderma suspectum</i> venom. Further evidence for an exendin receptor on dispersed acini from guinea pig pancreas", <i>J Biol Chem</i> , 267:7402-7405 (1992).	
		ENGLISH, "Food fails to suppress ghrelin levels in obese humans", <i>J Clin Endocrinol Metab</i> , 87:2984-87 (2002).	
		GHATEI, et al., "Molecular forms of human enteroglucagon in tissue and plasma: plasma responses to nutrient stimuli in health and in disorders of the upper gastrointestinal tract", <i>J Clin Endocrinol Metab</i> , 57:488-495 (1983).	
		KREYMANN, "Glucagon-like peptide-1 7-36: a physiological incretin in man", <i>Lancet</i> , 2:1300-1304 (1987).	
		TATEMOTO, "Isolation and characterization of peptide YY (PYY), a candidate gut hormone that inhibits pancreatic exocrine secretion", <i>Proc. Natl. Acad. Sci.</i> , 79:2514-8 (1982).	
		UESAKA, et al., "Glucagon-like peptide isolated from the eel intestine: effects on atrial beating", <i>J Exp Biol.</i> , 204(Pt 17):3019-26 (2001).	
		WREN, et al., "Ghrelin enhances appetite and increases food intake in humans", <i>J Clin Endocrinol Metab</i> , 86:5992-5 (2001).	
		WYNNE, et al., "Subcutaneous oxyntomodulin reduces body weight in overweight and obese subjects: a double-blind, randomized, controlled trial", <i>Diabetes</i> , 54(8):2390-5 (2005).	

Examiner's Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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J034 Rec'd PCT/PTO 08 NOV 2005 PCT

PTO/SB/21 (09-04)

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 10/541,526

Filing Date July 7, 2005

First Named Inventor Stephen Robert Bloom

Art Unit 1646

Examiner Name

Attorney Docket Number AI 9250 US

**ENCLOSURES (Check all that apply)**

- |   |   |   |
|---|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form                  | <input type="checkbox"/> Drawing(s)                                       | <input type="checkbox"/> After Allowance Communication to TC                            |
| <input type="checkbox"/> Fee Attached                                     | <input type="checkbox"/> Licensing-related Papers                         | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply                                  | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final                                      | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)                        | <input type="checkbox"/> Power of Attorney, Revocation                    | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                        | <input type="checkbox"/> Change of Correspondence Address                 | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Express Abandonment Request                      | <input type="checkbox"/> Terminal Disclaimer                              | Three (3) pages of PTO-1449;  |
| <input checked="" type="checkbox"/> Information Disclosure Statement      | <input type="checkbox"/> Request for Refund                               | twenty-eight (28) references; return  |
| <input type="checkbox"/> Certified Copy of Priority Document(s)           | <input type="checkbox"/> CD, Number of CD(s) _____                        | postcard  |
| <input type="checkbox"/> Reply to Missing Parts/Incomplete Application    | <input type="checkbox"/> Landscape Table on CD                            |   |
| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 |   |   |

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Pabst Patent Group LLP		
Signature	<i>Rivka D. Monheit</i>		
Printed name	Rivka D. Monheit		
Date	November 4, 2005	Reg. No.	48,731

**CERTIFICATE OF TRANSMISSION/MAILING**

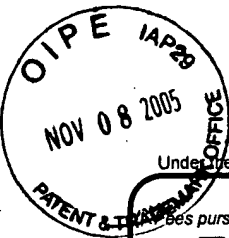
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	<i>Ronna Berman</i>		
Typed or printed name	Ronna Berman	Date	November 4, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

### Complete if Known

Application Number	10/541,526
Filing Date	July 7, 2005
First Named Inventor	Stephen Robert Bloom
Examiner Name	
Art Unit	1646
Attorney Docket No.	AI 9250 US

### METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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### FEE CALCULATION

#### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

#### 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
24 - 24 or HP = 0 x						
HP = highest number of total claims paid for, if greater than 20						
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)			
3 - 3 or HP = 0 x						
HP = highest number of independent claims paid for, if greater than 3						

#### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x		

#### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other:

Fees Paid (\$)

#### SUBMITTED BY

Signature	<u>Rivka D. Monheit</u>	Registration No. (Attorney/Agent)	48,731	Telephone	(404) 879-2152
Name (Print/Type)	Rivka D. Monheit			Date	November 4, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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